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ABSTRACT

The advisory report for professionals and public concerns the use of stimulant medications in treating elementary school-age children with behavioral disturbances. The discussion of the nature of children's behavioral disorders focuses upon hyperactivity, often termed minimal brain dysfunction or hyperkinetic behavioral disturbance, which is often treated with stimulant drugs. Incidence, causes, course, and diagnosis of hyperkinetic disorders are summarized, and drug treatment and its degree of success reviewed. Concerns voiced by the public and the media about hazards and abuses when stimulant medications are used for children are discussed and some misconceptions clarified. It is concluded that stimulant drugs are a valid method of treatment in hyperkinetic behavioral disorders, but not the only effective form of treatment. Expanded programs of continuing education and research are recommended. (KW)



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REPORT OF THE CONFERENCE ON THE USE OF STIMULANT DRUGS IN THE TREATMENT OF BEHAVIORALLY DISTURBED YOUNG SCHOOL CHILDREN

INTRODUCTION

On January 11-12, 1971, the Office of Child Development and the Office of the Assistant Secretary for Health and Scientific Affairs, Department of Health, Education, and Welfare, called a conference to discuss the use of stimulant medications in the treatment of elementary school-age children with certain behavioral disturbances. In convening the conference, the Office of Child Development was aware of public concern about the increasing use of stimulant medications (such as dextroamphetamine and methylphenidate) in treating so-called hyperkinetic behavior disorders. Were these drugs--so widely misused or abused by adolescents and adults--truly safe for children? Were they properly prescribed, or were they used for youngsters who, in fact, need other types of treatment? Is emphasis on medications for behavior disorders misleading? Might this approach tempt many to oversimplify a complex problem, leading to neglect of remedial social, educational or psychological efforts on the part of professionals, parents, schools and public agencies?

In order to clarify the conditions in which these medications are beneficial or harmful to children, to assess the status of current knowledge, and to determine the best auspices for administering these drugs to children, a panel of fifteen specialists was invited to meet in Washington. The panelists were from the fields of education, psychology, special education, pediatrics, adult and child psychiatry, psychoanalysis, basic and clinical pharmacology, internal medicine, drug abuse and social work. The panel's task was to review the evidence of research and experience and to prepare an advisory repert for professionals and the public.

This report briefly outlines the general nature of behavioral disorders in children and then focuses on those disorders that are being treated with stimulant medications. It discusses appropriate treatment and the concerns voiced by the public and media. Finally, the report examines the role of the pharmaceutical industry, professionals, and the news media in publicizing stimulant drugs for children and outlines the glaring gaps in needed research, training and facilities.

BEHAVIOR DISORDERS OF CHILDHOOD

A wide range of conditions and disabilities can interfere with a child's learning at home and in school, his socialization with peers, and his capacity to reach his maximum development. Social deprivations and stress at home or school may retard optimal development. Mental retardation, the more rarely occurring childhood autism and psychosis, and other such disabilities may cause serious problems. Some difficulties arise because of clearly definable medical conditions such as blindness, deafness or obvious brain dysfunction. Some are associated with specific reading or perceptual defects, and others with severe personality or emotional disturbance.

Such dysfunctions are known to require careful evaluation, thoughtfully planned treatment employing a variety of methods on the child's behalf, and conscientious monitoring of remedial treatments. Individualized evaluation and treatment is important for any childhood behavior disorder. There are appropriate occasions for use of medications such as tranquilizers and anti-depressants in some children with these disorders. For over three decades, stimulant

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medications have been selectively used for children under medical supervision. We now focus upon issues related to the current use of these drugs.

"HYPERKINETIC DISORDERS"

The type of disturbance which has evoked misunderstanding and concern has many names. The two most familiar--neither entirely satisfactory--are "minimal brain dysfunction" or, more commonly, "hyperkinetic behavioral disturbance." There is no known single cause or simple answer for such problems. The major symptoms are an increase of purposeless physical activity and a significantly impaired span of focused attention. The inability to control physical motion and attention may generate other consequences, such as disturbed mood and behavior within the home, at play with peers, and in the schoolroom.

In its clear-cut form, the overt hyperactivity is not simply a matter of degree but of quality. The physical activity appears driven--as if there were an "inner tornado"--so that the activity is beyond the child's control, as compared to other children. The child is distracted, racing from one idea and interest to another, but unable to focus attention.

INCIDENCE OF HYPERKINETIC DISORDERS

This syndrome is found in children of all socioeconomic groups and in countries throughout the world. A conservative estimate would be that moderate and severe disorders are found in about 3 out of 100 elementary school children--an estimate that would vary somewhat in different communities. More males than females are affected, as is true in a number of childhood ailments. Children so afflicted are generally of normal or superior intelligence. A significant number so diagnosed have special learning or reading disabilities, in addition to the major symptoms. A near majority are reported to have had behavioral problems since infancy. There is a smaller group of more severely afflicted children upon whom most studies have focused; they may show increased clumsiness and a variety of physical symptoms. Thus, some of the children show hyperactivity and reduced attention which ranges in degree from mild to severe, with or without associated physical signs or special learning impairments; some have complex behavioral and personality problems, as well as special learning and reading difficulties, along with the major hyperkinetic symptoms.

CAUSES OF HYPERKINETIC DISORDERS

We know little about definitive causes. The disorder has been ascribed to biological, psychological, social or environmental factors, or a combination of these. There is speculation that the core set of symptoms--those affecting control of attention and motor activity--may have their origin in events taking place before the child is born, or during the birth process, or they may be related to some infection or injury in early life. The neurological and psychological control of attention is an important but incompletely researched topic, as are the nutritional, perinatal and developmental factors. Thus, in many instances, it is not yet possible even to speculate as to original causes.

THE COURSE OF HYPERKINETIC DISORDERS

Usually, the excessive activity and attentional disturbances are less apparent after puberty. Specialists citing experience and some fragmentary research data believe that treatment enables many to lead productive lives as adults, while severely afflicted children who remain untreated may be significantly at risk for adult disorders. Extensive research is still required on these points. Because the ages of 5 to 12 are crucial to the child's development and self-image, treatments which permit the child to be more accessible to environmental resources are warranted and useful.



DIAGNOSIS OF HYPERKINETIC DISORDERS

In diagnosing hyperkinetic behavioral disturbance, it is important to note that similar behavioral symptoms may be due to other illnesses or to relatively simple causes. Essentially healthy children may have difficulty maintaining attention and motor control because of a period of stress in school or at home. It is important to recognize the child whose inattention and restlessness may be caused by hunger, poor teaching, overcrowded classrooms, or lack of understanding by teachers or parents. Frustrated adults reacting to a child who does not meet their standards can exaggerate the significance of occasional inattention or restlessness. Above all, the normal ebullience of childhood should not be confused with the very special problems of the child with hyperkinetic behavioral disorders.

The diagnosis is clearly best made by a skilled observer. There unfortunately is no single diagnostic test. Accordingly, the specialist must comprehensively evaluate the child and assess the significance of a variety of symptoms. He considers causal and contributory factors—both permanent and temporary—such as environmental stress. He distinguishes special dysfunctions such as certain epilepsies, schizophrenia, depression or anxiety, mental retardation or perceptual deficiencies. The less severe and dramatic forms of hyperkinetic disorders also require careful evaluation. Adequate diagnosis may require the use not only of medical, but of special psychological, educational and social resources.

TREATMENT PROGRAMS

The fact that these dysfunctions range from mild to severe and have ill-understood causes and outcomes should <u>not</u> obscure the necessity for skilled and special interventions. The majority of the better known diseases--from cancer and diabetes to hypertension--similarly have unknown or multiple causes and consequences. Their early manifestations are often not readily recognizable. Yet useful treatment programs have been developed to alleviate these conditions. Uncertainty as to cause has not prevented tests of the effectiveness of available treatments, while the search for clearer definitions and more effective kinds of therapy continues. The same principles should clearly apply to the hyperkinetic behavior disorders.

Several approaches now appear to be helpful. Special classes and teachers can be directed to specific learning disabilities and thus restore the confidence of the child who experiences chronic failure. Modification of behavior by systematic rewarding of desired actions has been reported to be useful in some children. Elimination of disturbing influences in the family or classroom through counseling may often tip the balance, and a happier child may show improved control and function.

There will be children for whom such efforts are not sufficient. Their history and their examination reveal symptoms of such a driven nature that skilled clinicians undertake a trial of medical treatment. Medicine does not "cure" the condition, but the child may become more accessible to educational and counseling efforts. Over the short term and at a critical age, this can provide the help needed for the child's development.

Stimulant medications are beneficial in only about one-half to two-thirds of the cases in which trials of the drugs are warranted. The stimulant drugs are considered to be the first and least complicated of the medicines to be tried. Other medications—the so-called tranquilizers and anti-depressants—are generally reserved for a smaller group of patients. Without specialized medical therapy, the consequences for these children of their failure to manage—even in an optimal environment—are clearly very severe. In such cases, the aim is not to "solve problems with drugs," but to put the severely handicapped child in a position to interact with his environment to the extent that his condition permits.

Response to stimulant medication cannot be predicted in advance. Fortunately, the issue can be resolved quickly. When stimulants are given in adequate doses, a favorable response--when it occurs--is fairly rapidly obtained and is unmistakably the consequence of the drug. Thus, if an adequate test of pharmacotherapy (a few days or weeks) produces only doubtful benefits or none at all, treatment can be promptly terminated. The physician will,



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of course, adjust dosage carefully to assure an adequate therapeutic trial. It would be tragic to deprive a child of a potentially beneficial treatment by inattention to dose. Thus, it is clear that not all affected children require medication and that of those who do, not all respond.

When the medication is effective, the child can modulate and organize his activities in the direction he wishes. The stimulant does not slow down or suppress the hyperkinetic child in the exercise of his initiative. Nor does it "pep him up," make him feel high, overstimulated, or out of touch with his environment. Much has been made of the "paradoxical sedative" effect of stimulants in such children. The term is inappropriate. Although their exact mechanism of action is not known, stimulants do not provide a chemical straitjacket. They do not act as a sedative. Rather, they appear to mobilize and to increase the child's abilities to focus on meaningful stimuli and to organize his bodily movements more purposefully.

The hoped-for secondary consequences are better peer relationships, improved self-image, and pleasure in acquiring competencies. Any coexisting dysfunctions—such as special perceptual and learning handicaps—must not be left unattended, simply because pharmaco—therapy is available and sometimes helpful. Similarly, personality and psychological problems, social and family problems, may require continued attention.

During drug treatment, the dosage may require shifting to minimize unwanted effects, of which the major ones are loss of appetite and insomnia. Drug treatment should not and need not be indefinite, and usually is stopped after the age of 11 or 12. Frequently, following a sustained improvement over several months or a year or so, drugs may be discontinued, as during a vacation period. Drug-free intervals can be prolonged as observers assess the child's condition.

The decision to use drug treatment thus depends on the commitment to diagnose and to monitor the response to treatment in the best traditions of medical practice. When there is informed parental consent, parents, teachers and professionals can collaborate in organizing and monitoring treatment programs.

CONCERNS RAISED BY THE PUBLIC AND THE NEWS MEDIA

We will now turn to various concerns about hazards and abuses when stimulant medications are used for children. For example, concern has been expressed that the medical use of stimulants could create drug dependence in later years or induce toxicity. This subject touches on the rights of the child to needed treatment, as well as risks to both the child and the public, and requires continued intensive scrutiny.

1. Does the medication produce toxicity?

One should not confuse the effects of intravenous stimulants and the high dosages used by drug abusers with the effects or the risks of the low dosages used in medical therapy. In the dosage used for children, the questions of acute or chronic toxicity noted in the stimulant abuser are simply not a critical issue. Unwanted mental or physical effects do rarely appear in children; cessation of therapy or adjustment of dosage quite readily solves the problem.

2. Is there a risk of drug dependency in later years?

Thirty years of clinical experience and several scientific studies have failed to reveal an association between the medical use of stimulants in the pre-adolescent child and later drug abuse. Physicians who care for children treated with stimulants have noted that the children do not experience the pleasurable, subjective effects that would encourage misuse. They observe that most often the child is willing to stop the therapy, which he views as "medicine." Thus, the young child's experience of drug effects under medical management does not seem to use misuse. The medical supervision may "train" him in the appropriate use of medicines.

When adults are given stimulants—or even opiates—for time-limited periods under appropriate supervision and for justifiable reasons, there is relatively little misuse. Similarly, in treating epilepsy, barbiturates have been given from infancy to adulthood without creating problems of dependency or abuse.

It is not ordinarily the drug which constitutes abuse but the way in which a drug and its effects are used and exploited by an individual. There are indeed adolescents who, in varying degrees and for varying periods of time, either misuse or dangerously abuse stimulants. They experiment with the effects of excessive dosages to create excitement, to avoid sleep, to defy constraints, and to combat fatigue and gloom. It should be noted that these drugs are not commonly prescribed to children after the age of 11 or 12, when the actual risks of such experimentation or misuse might possibly become more significant.

Alter monitoring of drug use at any age is a part of sensible medical practice. With such precaution and with the available evidence, we find minimal cause for concern that treatment will induce dangerous drug misuse. To the contrary, there are very good reasons to expect that help, rather than harm, will be the result of appropriate treatment.

3. Are there safeguards against misuse?

There are some sensible steps, in addition to medical control, that guard against possible misuse. The child should not be given sole responsibility for taking the medication. He usually need not bring the drug to school. The precautions that surround the medicine cabinet—whether antibiotics, aspirins, sedatives or other medications are present—should be applied. Many such medicines, when misused, can be more dangerous to health and life than even the stimulant drugs. No child in the family should have ascess to medications not prescribed for him. These are general precautions comprising a part of the child's education in the "etiquette of the medicine cabinet."

4. Do stimulants for children create a risk for others?

The panel agrees that stimulant drug abuse is seriously undesirable and not infrequently dangerous, although views vary on the scope of the problem and the number of actual casualties. Experts also agree that far more stimulants are prescribed for adults than are medically needed and far more are manufactured than prescribed. Overprescription of any medication is deplored, whether or not it is liable to abuse. The question is whether the availability of stimulants for a very few of the childhood behavior disorders threatens the public health.

The prescribed dosage for an individual child constitutes an insufficient quantity to supply the confirmed abuser of stimulants with the amounts he requires. It is also true that illicitly manufactured stimulants are quite readily available and abused in this country. We must weigh the advantages of having appropriate medication available against the dangers of withholding treatment from a child who can clearly benefit from it. We doubt that prescriptions for the children who benefit from stimulants will require the manufacture of excessive and dangerously divertible supplies. With sensible precautions, there is at present no evidence justifying sensational alarm, either about the safety of the individual child who can benefit from therapy or about the safety of the general public.

5. Does medication handicap the child emotionally?

It is sometimes suggested that treated children may not be able to learn normal responses and master adjustments to the stresses of everyday life. These fears are understandable but are not confirmed by specialists who have experience with the conditions and the situations in which medications are properly used. For the correctly diagnosed child, these medications—if they work at all—facilitate the development of the ability to focus attention and to make judgments in directing behavior. Such children can acquire the capacity to tolerate and master stress. The medications, in these circumstances, help "set the stage" for satisfactory psychological development.



The hyperkinetic behavioral disturbance is a form of disorganization that creates great

stress in the afflicted child. The use of therapeutic stimulants for this disturbance should not be equated with the misuse of medication aimed at allowing a normal child or adult to avoid or escape the ordinary stresses of life.

6. What are the rights of the parents?

Under no circumstances should any attempt be made to coerce parents to accept any particular treatment. As with any illness, the child's confidence must be respected. The consent of the patient and his parents or guardian must be obtained for treatment. It is proper for school personnel to inform parents of a child's behavior problems, but members of the school staff should not directly diagnose the hyperkinetic disturbance or prescribe treatment. The school should initiate contact with a physician only with the parents' consent. When the parents do give their approval, cooperation by teachers, social workers, special education and medical personnel can provide valuable help in treating the child's problem.

STIGMATIZING THE MEDICINES AND CHILDREN, AND THE ROLE OF PUBLIC EDUCATION

A child who benefits from stimulants or other psychotropic medications should not be stigmatized; his situation is no different from that of the child who benefits from eyeglasses. It is unjust to stigmatize a child in later life, when competing in various situations (applying for college, employment or organization memberships), by labeling him early in life as "stupid," an "emotional cripple," a "drug-taker," or by any other kind of unjustified and unfortunate stereotype.

Nor should the medicine be stigmatized. Where bad practices prevail—and a number of complaints have been called to our attention—these practices should be squarely dealt with. This is not only a responsibility of physicians and educators, but also of the news media. Yet indignation must be tempered with perspective and scrupulous respect for the facts. An informed and understanding public can foster the growth and development of children, and these public attitudes may lead to the development of more refined and better-delivered health services. Either bad practices or exaggerated alarm can threaten the availability of medical resources for those who critically need it. This has happened before in the history of valuable medicines, and it can take years to repair the damage.

THE PROMOTION OF DRUGS BY INDUSTRY AND THE MEDIA

Pharmaceutical companies producing stimulants or new medications which may become useful for hyperkinetic disorders have a serious obligation to the public. These medicines should be promoted ethically and <u>only</u> through medical channels. Manufacturers should not seek endorsement of their products by school personnel. In the current climate, society can best be served if industry refrains from any implicit urging that nonspecialists deal with disorders and medications with which they are unfamiliar. Professionals and the news media can play useful roles by not pressing for treatments in advance of their practical availability.

THE DELIVERY OF SPECIAL HEALTH CARE: A DILEMMA

Our society has not as yet found complete solutions to the problem of the delivery of special health care. When available treatments cannot be confidently and appropriately delivered by physicians, they are perhaps best withheld until such treatments can be provided—especially with milder dysfunctions. This is not to say that severely afflicted hyperkinetic children should not or cannot receive available medical treatment. But until systems of continuing professional education and ready access to consultants are financed and perfected, some judgment about the pace at which unfamiliar treatments can be widely fostered is required. Finally, we must recognize that it is not only the scarcity of trained personnel, but factors such as poverty and inadequate educational facilities which prevent accessibility to "d"—idualized treatment.

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THE NEED FOR SKILLS AND KNOWLEDGE

In preparing this report, the Committee was repeatedly struck by our lack of information in many crucial areas. The facts are that children constitute well over half our population, but receive a disproportionately low share of skilled research attention. We have noted the difficulties in arriving at accurate methods of diagnosis and the importance of launching careful longitudinal and follow-up studies. The investigation of causal factors lags. Such factors as perinatal injury, environmental stress or the development of the neurological and psychological controls of attention require study. Variations in different socioeconomic and ethnic groups must be considered in order to arrive at better definitions of behavior properly regarded as pathological. All such research efforts would have aided us in assessing the numbers of affected children and in recommending designs for more effective treatment programs.

Clinical pharmacologists have repeatedly found that drugs may act differently in children than in adults. To use medicines of all kinds effectively in children, more specialists must be trained in drug investigation--pharmacologists who can develop basic knowledge about the action of drugs in the developing organism. There is the obvious need for better and more precisely targeted drugs for the whole range of severe childhood behavior disorders. This requires intense research and training efforts. Such efforts provide the means for developing, testing and delivering better treatment programs. There is a similar need for research in the techniques of special education and also a need to make these techniques available to children who can benefit. It would appear to be a sound Federal investment to conduct such research and training.

In summary, there is a place for stimulant medications in the treatment of the hyperkinetic behavioral disturbance, but these medications are not the only form of effective treatment. We recommend a code of ethical practices in the promotion of medicines, and candor, meticulous care and restraint on the part of the media, professionals and the public. Expanded programs of continuing education for those concerned with the health care of the young, and also sustained research into their problems, are urgently needed.

Our society is facing a crisis in its competence and willingness to develop and deliver authentic knowledge about complex problems. Without such knowledge, the public cannot be protected against half-truths and sensationalism, nor can the public advance its concern for the health of children.



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